

Message Text

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20

ORIGIN HEW-06

INFO OCT-01 AF-06 EUR-12 EA-10 NEA-09 ISO-00 OES-05 /049 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EA/RA:CCHAPMAN INFO

AF/W:RJDOLS INFO

NEA/IAI:EWBIZIC INFO

EUR/NSC-IG:JROUSE INFO

NEA/INS:BBROWN INFO

----- 044767

R 251910Z FEB 75

FM SECSTATE WASHDC

TO AMEMBASSY VIENNA

AMEMBASSY TAIPEI

AMEMBASSY HELSINKI

AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY NEW DELHI

AMEMBASSY TEL AVIV

AMEMBASSY ROME

AMEMBASSY TOKYO

AMEMBASSY THE HAGUE

AMEMBASSY WELLINGTON

AMEMBASSY OSLO

AMEMBASSY LISBON

AMEMBASSY PRETORIA

AMEMBASSY MADRID

AMEMBASSY STOCKHOLM

AMEMBASSY BERN

AMEMBASSY LONDON

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E.O. 11652: N/A

TAGS: OGEN, EIND, ETRD, TBIO, AU, TW, FI, FR, GW, IN, IS, IT,

JA, NL, NZ, NO, PO, SF, SP, SW, SZ, UK

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SUBJECT: FDA ADVISORY - IN VITRO DIAGNOSTIC REAGENT

1. FDA ADVISES THAT THE PRODUCT "GLUSALASE" LIQUID ENZYME PREPARATION, MANUFACTURED BY ENDO LABORATORIES, INC., 1000 STEWART AVENUE, GARDEN CITY, NEW YORK 11530, A PREPARATION CONTAINING GLUCRUONIDASE AND SUFATASE, USED AS AN IN VITRO DIAGNOSTIC REAGENT TO FACILITATE STEROID ANALYSIS IS SUB-POTENT WITH RESPECT TO THE ACTIVITY OF THE SULFATASE ENZYME. THE LABELS FOR THE LOTS LISTED BELOW REFLECT A VALUE FOR SULFATASE UNITS DOUBLE THE ACTUAL VALUE. THE GLUCRUONIDASE UNITS ARE CORRECT AS LABELED.

2. THE PRODUCT IS PACKAGED IN 1 ML., 10 ML, AND 500 ML VIALS, WITH UNIT CARTONS AND PACKAGE INSERTS. VIALS AND CARTONS ARE SIMILARLY LABELED "GLUSALASE"; EACH ML. CONTAINING XXX UNITS GLUCRUONIDASE XXX UNITS SULFATASE XXX FOR LABORATORY USE ONLY XXX DIAGNOSTIC REAGENT, ENDO LABORATORIES INC., GARDEN CITY, NEW YORK 11532. THE ONE ML. VIAL IS ALSO PACKAGED IN A 6-UNIT SLEEVE BOX SIMILARLY LABELED. SINCE THE PRODUCT IS OF NATURAL ORIGIN (EXTRACTED FROM SNAILS), THE ENZYME QUANTITY OF EACH LOT IS DIFFERENT. THE LABELED QUANTITY OF UNITS OF GLUCRUONIDASE AND SULFATASE VARIES FROM LOT TO LOT, BASED ON THE FIRM'S ANALYSIS.

3. THE FOLLOWING LOTS ARE INVOLVED: BOO96A, BOO96B, BOO96C, DEO61A, DEO61B, BEO61C, EDO54A, EDO54B, EDO54C, EO152A, E0152B, EO152C, FH158A, FH158B, FH160A, FJ182A, FJ183A, HAO43A, HAO43B, HAO43C, HCO272A, HCO72B, HF117C.

4. LETTERS WERE MAILED BY THE FIRM TO ALL CONSIGNESS ON DECEMBER 30, 1974 AND AGAIN ON JANUARY 6, 1975. POSTS ARE REQUESTED TO ASCERTAIN WHETHER FOREIGN CONSIGNEES HAVE RECEIVED LETTERS REGARDING THIS PRODUCT.

5. FOREIGN CONSIGNEES, AS FOLLOWS:

INST ALLGEMEINE B10 WAHRINGERSTRASSE 38, A 1090, WIEN, AUSTRIA
DIPL ING ZOLTAN SZA, KALBECKGASSE 5, VIENNA, AUSTRIA
DR. H. KATINGER MICHELERSTRASSE 25, A1180, WIEN, AUSTRIA
B10 GESELLSCHAFT, BRUNNER ST. 59, A 1235, WIEN, AUSTRIA
YUNG HUNG HONG, 23 WUCHANG S ST., SEC 1, TAIPEI, TAIWAN
TAIWAN SUGAR RSCH, 54 SHENG CHAN RD., TAINAN, TAIWAN
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ORION PHARMACEUTICA, NILSIANKATU 10, HELSINKI, FINLAND
YLIOPISTON APTEEKKI, KALLIOLANRINNE 8, HELSINKI 51, SUOMI,
FINLAND
FLOBIO SOC A RESPON, 31 33 RUE DE LAMBRECHTS, 92400 COURBEVOIE,
FRANCE
LAB DE BIOLOGIE, CELLULAIRE 4, BATIMENT 444, ORSAY, FRANCE
LAB DE GENETIQUE, UNIV PAUL SABAITER, 118 RT NARBONNE,
31 TOULOUSE, FRANCE

TOUZART MATIGNON, 3 RUE SMYOT, PARIS 5, FRANCE
ECONOMAT CENTRAL RUE DE LA CITE, 6001 MARCINELLE, FRANCE
INST GUSTAVE ROUSSY, 16 BIS AV., 94 VILLEJUIF, PARIS, FRANCE
FOUNDATION CURIE, INSTITUT DU RADIUM, 15 RUE GEORGE C,
ORSAY, FRANCE
BERL HADLES KONTOR, 1 BERLIN 65, REINICKENDORFER, STR 5,
GERMANY
INST FUR BOPHYSIK, STRAHLENZENTRUM, 63 GLEBEN, GERMANY
THE REGISTRAR INDIAN INSTITUTE OF SCI., BANGALORE 12, INDIA
DR. S.K. SEN, RSCH UNIT, BANARAS HINDU UN, VARANASI, INDIA
JAWAHAPLAL NEHRU UN SCHL LIFE SCIENCES, NEW MEHRAULI RD.,
NEW DELHI, INDIA
TECHNION ISRAEL INS. OF TECHNOLOGY, TECHNION CITY, HAIFA,
ISRAEL
INST. DI CHIMICA B10, UNIV DI TRESTE, VALERIO 32, 34127,
TRIESTE, ITALY
INTERNATIONAL LAB., 80125 NAPOLI, ITALY
NAGOYA UNIV B10 INS, FACULTY OF SCI., NAGOYA, JAPAN
WAKAMORI SHOKAI LTD., 10 JO HIGASHI 3, SAPPORO 063, JAPAN
DEUTSCU CHEM. PHARM., CPO BOX 1153, OSAKA, JAPAN
OSAKA CITY UNIV., DEPT OF BIO, OSAKA, JAPAN
KOKUSAI KINSOKU KOH SHIBUYA SHIBUYA KU, TOKYO, JAPAN
DEPT OF BIOLOGY, FACULTY OF SCI., KONAN UNIV., KOBE 658, JAPAN
BRUNSCHWIG CHEMIE, KELZERSGRACHT 716, AMSTERDAM C, NETHERLANDS
PLAMERTON N HOSP., P.O. BOX 607, PALMERSTON NORTH, NEW ZEALAND
SCIENTIFIC IND, 86 ST. ANDREW ST., DUNEDIN, NEW ZEALAND
UNIV. OF BERGEN, PHARMACOLOGY DEPT., MFH BYGGET, BERGEN, NORWAY
LAB DE MICROBIO, CENTRO DE BIOLOGIA, INST. DE CIENCIA, DEIRAS
PORTUGAL
T.C. SCIENTIFIC SUPP, P.O. BOX 1366, JOHANNESBURG, S. AFRICA
BIO DE PROTEINAS, INS DE BIO CELULAR, VELAZQUEZ 144, MADRID 6,
SPAIN
UNIV. OF GOEBORG, CARL SKOTTSBERGS, GATA 22 S41319, GOTE-
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BORG, SWEDEN
AKTIEBOLAGET KABI, FACK S 104 25, STOCKHOLM 30, SWEDEN
CHEMIE BENSCHWIG AG, 4054 BASEL, SWITZERLAND, BELCHENSTRASSE 12
WANDER LTD BERNE, P.O. BOX 2747, CH 3001 BERNE, SWITZERLAND
ACCTS OFCE INVOICE S, IMPERIAL COLG OF SCI TECHNOLO, LONDON
S.W. 7, ENGLAND
KODAK LTD, ACORNFIELD RD., KIRKBY IND ESTAT, LIVERPOOL L
33 7UF
ROYAL HOLLOWAY COLL, UNIV. OF LONDON, ENGLEFIELD GREEN EGHAN
SURREY, ENGLAND
UNIV SUSSEX, SUSSEX HOUSE, FLAMER BRIGHTON, ENGLAND BN 1 9RH
DEPT OF FORESTRY, SOUTH PARKS RD., OXFORD, ENGLAND
UNIV. EDINBURGH, ROYAL INFIRMARY, EDINBURGH, SCOTLAND
KISSINGER

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NNN

Message Attributes

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Draft Date: 25 FEB 1975
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Disposition Approved on Date:
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Disposition Reason:
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05 JUL 2006

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Status: NATIVE
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TAGS: OGEN, EIND, ETRD, TBIO, FDA
To: VIENNA MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006